

PTO-1390 (Rev. 07-2005) Approved for use through 3/31/2007. OMB 0651-0021 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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## TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER AR&E Docket No. 96700/1120

CFR 1.5) **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** INTERNATIONAL APPLICATION NO. PCT/US2004/032675 INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED October 7, 2003 October 5, 2004 TITLE OF INVENTION TREATMENT OF COGNITIVE DYSFUNCTION IN LUPUS APPLICANT(S) FOR DO/EO/US Teresa P. DiLorenzo, Anne M. Evans, Donald F. Hunt, Scott M. Lieberman, Stanley G. Nathenson, Pere Santamaria, and Jeffrey Shabanowitz Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT 10 Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 12 v 13. A preliminary amendment. 14 An Application Data Sheet under 37 CFR 1.76. 15 A substitute specification. A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18 A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3



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10.5. APPLICATION NO. (if known, see 37 CFR 1.5)  10.5. APPLICATION NO. (if known, see 37 CFR 1.5)  10.5. APPLICATION NO. (if known, see 37 CFR 1.5)  10.5. APPLICATION NO. (if known, see 37 CFR 1.5)  10.5. APPLICATION NO. (if known, see 37 CFR 1.5)  10.5. APPLICATION NO. (if known, see 37 CFR 1.5)		AR&E Docket No. 96700/1120			
10/5/4994 FC1/032004/032073					
<sup>20.</sup> Other items or information: cover letter and return receipt postcard (enclosed)					
The following fees have been submitted			CALCULATIONS	PTO USE ONLY	
21. Sasic national fee (37 CFR 1.492(a))			\$ 300		
22. Examination fee (37 CFR 1.492(c))					
If the written opinion prepared by ISA/US or the interna	\$ 200				
by IPEA/US indicates all claims satisfy provision	•				
23. Search fee (37 CFR 1.492(b))					
If the written opinion of the ISA/US or the International IPEA/US indicates all claims satisfy provisions					
Search fee (37 CFR 1.445(a)(2)) has been paid on the	\$ 100				
International Searching Authority					
previously communicated to the US by the IB All other situations					
TOTAL OF 21, 22 and 23 =			600		
Additional fee for specification and drawings filed sequence listing in compliance with 37 CFR 1.					
electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets Extra Sheets Number of each additional 50 or fraction RATE					
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35 - 100 = 0 /50 =	35 - 100 = 0 /50 = x \$250		\$ 0		
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).			\$		
CLAIMS NUMBER FILED	NUMBER EXTRA	RATE	\$		
Total claims 20 - 20 =	0	x \$50	\$		
Independent claims 3 - 3 =	0	x \$200	\$		
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360			\$		
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Applicant claims small entity status. See 37 CFR					
Processing fee of \$130.00 for furnishing the English tree	\$ 300				
Processing fee of \$130.00 for furnishing the English tra- claimed priority date (37 CFR 1.492(i)).	\$				
	\$300				
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +			\$		
	\$ 300				
			Amount to be refunded:	\$	
			Amount to be charged	\$	

AR&E Docket No. 96700/1120

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NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.				
send all correspondence to: Craig J. Arnold, Esq. Amster, Rothstein & Ebenstein LLP 90 Park Avenue New York, NY 10016	SIGNATURE Elie H. Gendloff NAME 44,704 REGISTRATION NUMBER			
"Express Mail" mailing label No. EV 725786922 US Date of Deposit: April 6, 2006  I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450  Name: Elie H. Gendloff Signature:				

Intellectual Property Law

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April 6, 2006

Via Express Mail (EV 725786922 US)

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## 06 APR 2006

Norajean McCaffrey

Elie H. Gendloff, Ph.D., Esq. Direct 212 336 8108 E-mail egendlof@arelaw.com

EV 725786922 US "Express Mail" mailing label No. April 6, 2006 Date of Deposit: I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Elie H. Gendloff Name: Signature:

United States National Phase Filing of

PCT Application PCT/US2004/032675

TREATMENT OF COGNITIVE DYSFUNCTION IN LUPUS Title:

Applicants: Betty A. Diamond and Bruce T. Volpe

96700/1120 Our File:

Sir/Madam:

Pursuant to 35 U.S.C. § 371 and 37 C.F.R. § 1.495, enclosed please find an application for patent in the names of Betty A. Diamond and Bruce T. Volpe, entitled "TREATMENT OF COGNITIVE DYSFUNCTION IN LUPUS," for entering the national phase in the United States of America, comprising the following:

- a "Transmittal Letter to the United States Designated/Elected Office 1. (DO/EO/US) Concerning a Submission Under 35 U.S.C. § 371," Form PTO-1390 (3 pages with 3<sup>rd</sup> page in duplicate);
- a copy of PCT Application No. PCT/US2004/032675 as published 2. under PCT Publication No. WO 2005/037301 A1, including cover page with Abstract (1 page), specification (24 pages), claims (4 pages) and drawings (6 sheets);
- a Preliminary Amendment (6 pages); 3.

10/574994 IAPPROVERDED OF APR 2008

Commissioner for Patents Alexandria, VA 22313-1450 Mail Stop PCT -2-

April 6, 2006

- 4. an AR&E check in the amount of \$300 to cover the total filing fees, claiming small entity status; and
- 5. a return receipt postcard.

Please acknowledge receipt of the enclosed documents by stamping the enclosed postcard and returning the same to us.

Respectfully submitted,

Amster, Rothstein & Ebenstein LLP Attorneys for Applicants 90 Park Avenue New York, NY 10016 212 336 8000

Dated: New York, New York

April 6, 2006

Elie Gendloff

Registration No. 44,704